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JUL 27 2006

PATENT APPLN. NO. 10/761,806
SUBMISSION UNDER 37 C.F.R. § 1.114

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REMARKS

In the Final Office Action dated April 27, 2006, claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. (U.S. Patent No. 6,152,909; hereinafter "Bagaoisan") in view of Grasso, III et al. (U.S. Patent No. 6,375,651; hereinafter "Grasso") and in further view of Windischman et al. (U.S. Patent No. 2,716,983; hereinafter "Windischman").

Prior to discussing this rejection, applicants note that claim 1 has been amended to recite that the first cut surface of the cut surface extends from a proximal side of the neck-down tip. This limitation was recited in original claim 2 of the application filed on January 22, 2004, but was inadvertently omitted from claim 2 when claim 2 was presented in the preliminary amendment filed September 23, 2004.

Applicants respectfully submit that the cited references do not provide a proper motive to modify the catheter of Bagaoisan (as modified by Grasso) as proposed by the Office to include the cut surface of Windischman and to obtain the catheter of the present invention as now precisely recited in claim 1.

The catheter of the present invention is a thrombus suction catheter. Thrombus suction therapy is a therapeutic method of

inserting a tubule with a diameter of about 1.5 mm (referred to as a catheter) through a leg or arm to allow the catheter to reach a lesion portion in the coronary arteries, and removing a thrombus itself by suction (see paragraph [0004] of the present application). In the present invention, by forming a distal end opening so that at least a part of the proximal side of the opening as a thrombus suction port is concave and the distal end side flat and flexible, crossing is improved, a lesion portion expanded at the distal end opening can be covered, and suction is remarkably improved (see the abstract and paragraphs [0010] and [0042]).

Referring to the cited references, Bagaoisan does not disclose a cut surface, a portion of which on the proximal side is concave in the angled direction (as mentioned in the Office Action).

Grasso teaches a medical device including a suction conduit and an energy-transmitting conduit wherein at least some of the transmitted energy is directed to the distal region of the suction conduit. The device has applications in lithotripsy and tissue-removal in a patient (see, abstract). The device is inserted into a body lumen such as a ureter.

Once the suction conduit of the device of Grasso is operating, it keeps stones or stone fragments near its tip, stabilizing the movement of the stone (see, col.2, lines 31-33). The suction

conduit can be made of a variety of flexible and rigid materials or a combination of both, such as stainless steel or plastics (see, col.4 lines 61-62). The distal end 8 of the suction conduit 1 may assume any shape convenient for its intended use.... The face 7 may also assume a curved form, for example, ellipsoidal as shown in Fig 2C (see, col.2, lines 21-27).

From the descriptions in Grasso, the distal end of the suction conduit is different from the opening in the catheter of the present invention, that is, the opening in the catheter of the present invention cannot keep stones or stone fragments near its tip and stabilize the movement of the stone because the portion of the cut surface on the proximal side is concave in the angled direction in the present invention. Further, the laser lithotripsy device with suction in Grasso does not comprise a lumen for a guidewire. Therefore, the material of the device is not as flexible as the thermoplastic elastomers cited in the present invention, (see paragraph [0027]). The guidewire of the catheter of the present invention is first inserted into vessels, which needs flexibility.

As mentioned above, it is difficult to modify the cut surface as taught by Bagaoisan with the concave cut surface as taught by Grasso for the purpose of providing easier access to target

materials being removed along the wall of a blood vessel because such access would not be reasonably expected by a person of ordinary skill in the art.

Regarding Windischman, the Office cites the term "catheter" as defined by Webster's dictionary. However, such interpretation is not proper because in the medical arts, a combination of a tube and a guidewire, which are used for medical treatment in a blood vessel, is termed a "catheter".

Windischman discloses a piercing needle which can pierce a rubber closure plug or an epidermal tissue. The cannula of the needle 1 comprises a stainless steel tube 2 having a lumen 3 extending longitudinally therethrough (see, col. 1, last line to col. 2, line 2). The end of the cannula is pointed to form a rubber piecing point 5 by an obliquely extending bevel surface 7 formed by grinding the end of the cannula at the desired angle to the longitudinal axis 9 of the cannula (see, col. 1, lines 2-6). The piercing action of the needle will not result in tearing or otherwise removing a small piece of diaphragm or skin where the needle enters and thereby cause the cannula to become clogged or the solution to become contaminated (see, col. 1, lines 22-26).

Although the Office mentions that Windischman has the purpose of providing a distal end opening structure to the lumen that helps

the lumen from becoming clogged, such purpose is not disclosed or suggested in the reference. The purposes of providing a distal end opening structure in the reference are for inhibiting coring, requiring low pressure to penetrate a diaphragm or the like, reducing the discomfort and difficulty of inserting the needle and inducing better resealing properties in a rubber diaphragm after withdrawing the needle, not for preventing the lumen from being clogged by a suctioned thrombus (see, col. 1, lines 32-42).

As the Office mentions, Windischman teaches that the needle has a first cut surface 7 angled in the proximal direction of the needle, a ledge surface 14 parallel to the longitudinal axis of the needle extending from the first surface in the proximal direction to a second cut surface 16 that is concave and angled in the proximal direction of the needle (Fig. 3, 4). However, the bevel surface makes an angle of approximately 12 degrees with the longitudinal axis of the cannula which has an outside diameter of 0.072 inch = 1.8 mm (see, col. 2, lines 37-41). That is, the needle has a sharpened edge that is provided for the purpose of piercing a diaphragm or skin. If the edge of the bevel is not sharpened, a rubber plug is torn or skin is removed to form pieces. On the other hand, if a thrombus suction catheter has such a

sharpened edge made of stainless steel, a patient's vasculature may be damaged by the edge.

Windischman does not indicate or suggest that a large suction force will be obtained in the concave portion of the cut surface of the needle disclosed therein when the athero in a vessel is covered with the concave portion.

For each of the above reasons, none of the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art provide a motive to modify the cut surface of the catheter of Bagaoisan as modified by Grasso with the concave cut surface as taught by Windischman.

Removal of the 35 U.S.C. § 103(a) rejection of the claims is in order and is respectfully solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated April 27, 2006, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of

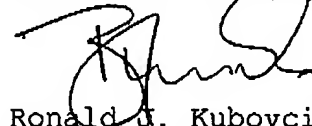
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time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,
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